

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AMENDED COMPLAINT

Plaintiff, Morton Grove Pharmaceuticals, Inc. (“Morton Grove”), by and through its attorneys, Winston & Strawn LLP, for its Amended Complaint against the National Pediculosis Association, Inc. (the “NPA”), states:

Nature of Action

1. This is an action brought to redress false, misleading, and deceptive statements and comparative advertisements regarding two FDA-approved drugs—Lindane Lotion and Lindane Shampoo—prescribed for the treatment of lice and scabies.

2. Plaintiff Morton Grove is a pharmaceutical company. Defendant NPA is the distributor of the LiceMeister® Comb, which competes with Lindane medications. While the NPA refers to itself as an “agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies”

pesticidal treatments” and masquerades as a health organization, upon information and belief, the NPA does not employ a single physician or licensed health professional. It is a competitor of Morton Grove. In fact, in 2003, 97% of the NPA’s revenues were derived through the sale of LiceMeister® combs.

3. Morton Grove brings this action against the NPA for violation of the Lanham Act, trade disparagement, and violation of the Illinois Deceptive Trade Practices Act.

4. Morton Grove is the only United States manufacturer and distributor of Lindane medications. As such, the NPA’s statements regarding “lindane” necessarily refer to Morton Grove and its products.

5. Lindane medications have been approved by the Food and Drug Administration (“FDA”) as safe and effective prescription therapy for the treatment of lice and scabies. These infections, some of which are sexually transmitted, are increasingly resistant to certain treatments and remain important public health problems that affect tens of millions of Americans each year.

6. In the 50+ years that Lindane medications have been on the market, subject matter experts working with the FDA and the Environmental Protection Agency (“EPA”) have reviewed the weight of medical and scientific evidence on Lindane medications and repeatedly determined that these medications are safe and effective when used as directed. The FDA has consistently maintained its position that the benefits of Lindane medications outweigh the risks—a factor for all medications—and should remain an option for physicians. Petitions, including

one filed by the NPA, to ban Lindane medications have repeatedly been denied and determined to be without merit.

7. Similarly, the EPA has concluded that pharmaceutical Lindane poses no significant risk to humans or the environment when used as currently labeled.

8. The public health benefits of Lindane medications are further supported by the recommendations of the Centers for Disease Control and Prevention (“CDC”). The CDC sets practice standards for the medical community and includes Lindane medications in its Sexually Transmitted Disease Treatment Guidelines for the management of scabies and pubic lice, consistent with the FDA-approved prescription labeling for Lindane Lotion and Lindane Shampoo.

9. Moreover, in 2003, important advancements to the packaging and prescription of Lindane medications manufactured and sold in the United States served to mitigate the potential risks associated with product misuse and further enhanced their public safety.

10. Lindane Lotion and Lindane Shampoo are named after their active ingredient, lindane. Historically, lindane was used primarily in an agricultural context—more than 99% of lindane was used agriculturally, while less than 1% was used pharmaceutically (e.g., 99.7% agricultural v. 0.3% pharmaceutical in 2006). The dangers associated with chronic occupational exposure to agricultural lindane have been widely and unfavorably reported. These dangers differ vastly from those associated with the short-term topical application of small amounts of Lindane medications to the hair and skin—just 4 minutes in the case of head lice.

11. Despite this well-documented scientific, medical, and regulatory history, the NPA has launched an attack campaign on Lindane medications. The NPA swaps agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminates false, misleading, and deceptive statements about the safety profile and effectiveness of Lindane medications. These statements have created confusion in the marketplace and affected purchasing and prescribing behavior, negatively impacting both the sale of Lindane medications and Morton Grove's business.

Parties

12. Morton Grove, a Delaware corporation, is a pharmaceutical company with its principal place of business in Morton Grove, Illinois.

13. Upon information and belief, the NPA, a Massachusetts corporation, is based in Needham, Massachusetts. The NPA widely distributes information and products nationally, including in Illinois, through its interactive websites www.headlice.org and www.lindane.org, which attract as many as 100,000 hits per day from thousands of unique visitors in the United States and around the world. The NPA sells its products nationally and has profited from the sales of the LiceMeister® comb in Illinois.

Jurisdiction & Venue

14. This Court has jurisdiction over the subject matter of this action based upon the federal question presented by the Lanham Act, 15 U.S.C. § 1125(a) *et seq.*, pursuant to 28 U.S.C. § 1331, and supplemental jurisdiction of the state law claims pursuant to 28 U.S.C. § 1337.

15. The Court has jurisdiction over the NPA based on their substantial contacts with the State of Illinois, including their commission of tortious acts which caused injury in the State of Illinois.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1331(b)(2).

Factual Allegations

I. Background on Lindane Medications

17. Morton Grove is the sole United States distributor of Lindane Shampoo and Lindane Lotion.

18. Lindane Lotion and Lindane Shampoo are prescription medications for the treatment of scabies, pubic lice, and head lice. These conditions are highly contagious public health conditions, some of which are sexually transmitted. These diseases affect adolescents, adults, and children, causing significant morbidity that impacts tens of millions of Americans.

19. Lindane medications have been used successfully in clinical practice for more than 50 years.

20. The FDA and the EPA, after numerous exhaustive reviews of the weight of evidence on Lindane medications, have concluded that currently approved

medical uses of Lindane medications do not pose a significant risk to public health or safety. In fact, Lindane medications have been reviewed by the FDA more than a dozen times beginning in 1951, and with each review the “FDA has determined that lindane products have benefits that outweigh risks when used as directed.” Woodcock, J. (Director, FDA Center for Drug Evaluation and Research), “Re: Docket No. 95P-0018/cP,” Correspondence to Jill A. Cashen, Cancer Prevention Coalition, May 13, 1997; U.S. Food and Drug Administration, Lindane Assessment Memorandum (2003). In 2001, the EPA even downgraded the cancer classification of lindane to a level that is in fact lower than the most commonly used first-line, over-the-counter medication permethrin (active ingredient in Nix®), and concluded that no additional cancer risk assessments of lindane in humans were necessary.

21. The CDC and the American Academy of Pediatrics (“APA”) both recommend pediculicidal treatments—which Lindane medications are considered—over wet combing for the management of head lice, as combing leads to dramatically lower rates of clinical cure than chemical treatments.

II. The NPA Attempts to Increase Sales of the LiceMeister® by Distributing False, Misleading, and Deceptive Advertisements Regarding Lindane Medications

22. Blindly ignoring well-established science and the positions of the FDA, EPA, CDC, and APA on Lindane medications, the NPA has launched an attack campaign against Lindane medications in the hopes that it can increase sales of the LiceMeister® comb. This for-profit campaign blatantly ignores all standards for comparative marketing, including those promulgated by the FDA’s Division of Drug

Marketing and Advertising, which prohibit all such advertisements unless the representations made in those advertisements are supported by substantial evidence derived from adequate and well-controlled studies. See 21 U.S.C. § 355(d). In addition, the NPA violates norms and rules of advertising established by the FTC. See 15 U.S.C. § 45; 15 U.S.C. § 52; 16 C.F.R. § 14.15. Examples of the NPA's false advertising claims and other false statements referenced infra are attached as Exhibit A. Recent NPA employees admitted in depositions that they have no scientific background or training, did nothing to verify that the posted material was correct, and did not vet the information with any scientists or licensed medical professionals.

23. On this commercial website, the NPA has posted several hundred MedWatch forms which it has completed. MedWatch forms are typically used by consumers and their healthcare providers to report to the FDA adverse experiences that consumers have had with various drugs. Here, the NPA solicits data from visitors to its website, uses that data to complete MedWatch forms, signs its name to these forms as the reporter, and submits the forms the FDA. Next to its name, the NPA indicates that it is a "Health professional."

24. In fact, the NPA is not a "Health professional"—none of the members of its Board of Directors and none of its employees are licensed healthcare professionals, such as physicians, pharmacists, or nurses. Nor does the NPA have any proximity to or involvement in the actual treatment of the patient, as is typical when a medical professional submits a MedWatch form. The repeated

representations that the NPA is a “Health professional” are false and misleading, contribute to the illusion of medical credentials that the NPA projects on its website, and are part of the context in which the NPA’s false statements were made.

25. The overall context and message of the NPA’s website, identified in Paragraph 13, and statements creates with the viewer a false impression that misrepresents: (1) Lindane medications’ effectiveness; (2) Lindane medications’ harm to the environment; (3) that if you use Lindane medications, you significantly increase the risks of developing cancer and other serious adverse health effects; and (4) the NPA’s statements are objective, represent the scientific norm, and come from scientifically- and medically-credentialed individuals.

26. In an effort to maximize profits, the NPA has falsely claimed that the “symptoms” from “exposure” to Lindane medications include:

acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional lability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.

27. In fact, the overwhelming majority of these so-called symptoms or side effects nowhere appear on the FDA-approved prescription label for Lindane Lotion or Lindane Shampoo and are not reflected in the events reported to the FDA through its Adverse Event Reporting System Database or to the manufacturer.

28. In addition to mischaracterizing the safety profile of Lindane medications, the NPA has also misclassified its regulatory status, claiming "Illinois Bans Lindane" and "Illinois Banned Lindane." The truth is that Illinois has not banned lindane. Following the filing of Morton Grove's complaint, the NPA removed these false statements from its website.

29. The NPA's website also falsely claims that "one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards."

30. Like many of the NPA's other statements, this statement is scientifically unsubstantiated and runs counter to the conclusions of subject matter experts working with the EPA. In fact, the EPA has determined in its most recent assessment of lindane that the amount of pharmaceutical lindane reaching drinking water supplies is insignificant and not of concern.

31. Even unrealistic, worst-case estimates show that if Lindane medications were dumped directly into the drinking water supply (and not washed down the drain and out of the water supply and then diluted many thousand fold when reintroduced into large bodies of water as would normally occur), lindane

levels would still be 67 to 333 times lower than the level considered safe by the EPA.

32. These findings are further reinforced by real-world data from large-scale water contamination studies which show that lindane is not a water contaminant of concern, and that levels—when rarely detected—are well below standards established by the EPA for safe drinking. For example, a 2003 survey of water contamination, which involved the testing of 16,000 water systems serving 100 million people across the US, conducted by the EPA found that 0% exceeded conservative levels considered safe. Federal Register 68(138) (July 18, 2003). Similar findings were noted by the United States Geological Survey in 1999 and 2000 where water samples near large cities and farms were tested across 30 states and all found to be well within established EPA standards. Kolpin DW, Furlong ET, Meyer MT, et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. streams, 1999–2000: A National Reconnaissance. *Environ Science Technology*, 2002; 36(6):1202–1211.

33. In addition, an almost identical statement was retracted by the NPA's former co-defendant, the Ecology Center, Inc., who noted that the EPA "does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use [of lindane] for both lice and scabies." See <http://www.ecocenter.org/safekids/clarifications.pdf>.

34. The NPA has received information from Morton Grove and others that its claim that "one dose of lindane" contaminates 6 million gallons of drinking water is false and misleading.

35. Despite knowledge of this statement's falsity, it remains on the NPA's website today.

36. The NPA does not stop there in its efforts to "scare" consumers into using its product, the LiceMeister® comb; it also attempts to convince consumers that using Lindane medications cause cancer. For example, it argues that: "[T]he U.S. EPA classif[ies] lindane as a possible human carcinogen" and "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION.**"

37. This statement is false and is not supported by the weight of scientific evidence or determinations published by the EPA, World Health Organization, and other subject matter experts.

38. In fact, the NPA's former co-defendant, the Ecology Center, Inc. issued a retraction noting that current information on the EPA's website notes that the EPA updated the cancer classification of lindane in 2003 to "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans." See <http://www.ecocenter.org/safekids/clarifications.pdf>

39. Lindane's carcinogenic risk is now considered by the EPA to be on par with malathion (active ingredient in FDA-approved lice treatment Ovide) and even lower than the most commonly used first-line, over-the-counter treatment permethrin (active ingredient in Nix).

40. The NPA also has stated: "Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos." There, however, have been no established links between the use of Lindane medications and the development of cancer, despite more than 50 years of clinical use on adults and children. The "case-controlled" research cited by the NPA prompted a special review by the FDA that subsequently concluded: "[I]t was unlikely that the data in the Davie et al. study established any link between the increased incidence of childhood brain cancer and the use of Lindane 1% . . . shampoo, and that there was no need to make any changes in the current labeling for [Lindane medications]."

41. The NPA has also claimed that: "Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death."

42. With respect to the NPA's allegation that the use of lindane medications is associated with leukemia, the NPA's former co-defendant, the Ecology Center, retracted a similar statement, which notes that in this particular study, only "[s]ix of the 568 children participating in this study were treated with lindane shampoo." As the Ecology Center conceded, the study's only conclusion with respect to lindane medications was that the issue "requires further study" in light of the "reported 95% confidence interval for lindane was CI 0.5 to 8.7," which

is not statistically significant.

See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

43. In a further effort to divert customers from Lindane medications to the LiceMeister® comb, the NPA's website also contains the following false and deceptive statements and misleading "warnings":

- "Be Sure You Provide a Non-Chemical Choice For Your Children . . . Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits."
- "Never resort to **dangerous remedies** such as lindane, kerosene, or pet shampoos." (emphasis supplied).
- "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."
- "Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective."

44. Finally, in an effort to sell additional LiceMeister® combs, the NPA has attempted to scare potential and actual consumers of Lindane medications with a "parade of horribles" regarding the effects of occupational exposure to agricultural lindane. These statements include:

- "Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems."
- "Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches,

convulsions, and disruption of the reproductive hormones of the endocrine system.”

45. These statements are wildly misleading in context, as the FDA has concluded that the “risk of occupational/environmental exposure should be assessed separately and independently of the risk related to the therapeutic use of a medication to treat a medical condition where there is a direct benefit to the patient.” The EPA shares this position.

46. Indeed, the NPA’s former co-defendant, the Ecology Center, Inc. published a retraction that clarifies this, noting that “the majority of such [adverse reactions] have resulted from oral ingestion (which is not how lindane medications are directed to be applied).”

See

<http://www.ecocenter.org/safekids/clarifications.pdf>.

47. Upon information and belief, the NPA has never performed, prior to publication of the aforementioned statements, any tests comparing the qualities and characteristics of the LiceMeister® comb and Lindane medications, or evaluating the qualities and characteristics of Lindane medications.

III. As a Result of the NPA’s Actions, Morton Grove Has Been Harmed

48. As a result of the NPA’s foregoing statements, Morton Grove has suffered incalculable financial and reputational injury to its business, including lost sales of Lindane medications and diminished goodwill.

49. The NPA’s statements, for example, contributed to a decrease in Morton Grove’s sales of 23%, or \$9.3 million, from January 2006 to November 2006.

50. The NPA's statements are viewed up to 100,000 times per day on the NPA's website, and they have deceived consumers and physicians into falsely questioning the safety and effectiveness of Lindane medications, thereby materially affecting purchasing and prescribing behavior for Lindane medications.

51. Moreover, the NPA has crafted its website in a manner to most effectively disseminate the aforementioned false and misleading statements, directing users to "see what we want them to see and avoid what we don't."

52. The NPA itself has acknowledged that its statements have affected Morton Grove's sales, noting that "sales figures for lindane products (Kwell, etc.) have fallen dramatically By targeting parents for re-education along with health professionals, we have ensured that the message travels up as well as down, and takes root in the process."

IV. The NPA's Statements Were Made Intentionally & Maliciously

53. In light of the statements' significant impact on Morton Grove's business, Morton Grove sent the NPA a letter (attached as Exhibit B) indicating that the NPA was publishing false, misleading, and deceptive statements about Lindane medications which were harming Morton Grove. This letter detailed each such false statement (either identical or similar to those included in this complaint), provided factual support for why each statement was false, and gave the NPA time to retract such statements. In addition, Morton Grove previously filed suit against the NPA on February 6, 2007 in the Northern District of Illinois (No. 06-CV-3815), from which this action was severed.

54. Despite this opportunity, the NPA failed to retract its false, misleading, and deceptive statements and continues to allow the publication and dissemination of these statements, even after receiving information that certain of these statements were false.

55. The NPA's continued publication of these statements, despite knowing their falsity, demonstrates the NPA's malicious intent to inflict harm on Morton Grove.

COUNT I
LANHAM ACT (15 U.S.C. § 1125(a))

56. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 55 of this Complaint.

57. The NPA sells a lice treatment product called the LiceMeister®, which it promotes as an alternative to Lindane medications.

58. The NPA's statements, through its website and sales of its product, have been made in interstate commerce and were, are, and continue to be made intentionally and willfully.

59. The NPA's advertising claims set forth above are false and misleading descriptions and representations of fact about Lindane medications. In addition, these statements are misleading in context and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

60. The NPA's false and misleading advertising claims have deceived and have the tendency to deceive a substantial portion of the target audience for lice and scabies treatments.

61. The NPA's false and misleading advertising claims are material to consumers' purchasing decisions.

62. The NPA has caused its false and misleading advertising claims to enter into interstate commerce.

63. The NPA's false and misleading advertising claims have caused certain consumers to not purchase Lindane medications. These claims have caused and are continuing to cause damage to Morton Grove's sales and market share and injury to Morton Grove's goodwill and business reputation, warranting injunctive relief.

64. The NPA's false and misleading claims were made deliberately and willfully, and the NPA knew or should have known that these statements were false and that the impact of its statements would be to reduce sales of Lindane medications. Therefore, Morton Grove seeks a finding that this is an exceptional case, requiring an award of attorney fees to Morton Grove.

65. The NPA's continued use of false or misleading advertising claims is causing great irreparable injury to Morton Grove, thereby warranting an order granting permanent injunctive relief.

COUNT II
TRADE DISPARAGEMENT

66. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 65 of this Complaint.

67. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 26 through 45.

68. The statements regarding Lindane medications set forth in Paragraphs 26 through 45 are false and misleading.

69. The NPA published and communicated these statements through its website and other means.

70. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove.

71. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 48 through 52.

COUNT III
ILLINOIS DECEPTIVE TRADE PRACTICES ACT (815 ILCS 510/2)

72. Morton Grove repeats and re-alleges the allegations set forth in Paragraphs 1 through 71 of this Complaint.

73. The NPA published and communicated to third persons the statements regarding Lindane medications set forth in Paragraphs 26 through 45.

74. The statements regarding Lindane medications set forth in Paragraphs 26 through 45 are false and misleading.

75. When the NPA published and communicated these statements and refused to retract them, it did so with knowledge of their falsity or reckless disregard for their truth, and with the intent to inflict economic harm upon Morton Grove. Specifically, prior to filing its Complaint, Morton Grove provided the NPA

with specific scientific proof that certain of its statements were false and misleading. The NPA did not substantively respond to Morton Grove's letter.

76. These statements violated multiple sections of 815 ILCS 510/2, including subsections (2), (7), (8), and (12).

77. As a result of the NPA's statements, Morton Grove suffered specific harm as detailed in Paragraphs 48 through 52.

WHEREFORE, Plaintiff, MORTON GROVE PHARMACEUTICALS, INC., requests this Honorable Court for the following relief:

A. An Order (i) permanently enjoining the NPA from further dissemination of false, misleading, and deceptive statements regarding Morton Grove and Lindane medications; (ii) permanently enjoining the NPA from future publication of the false, misleading, and deceptive statements contained in Paragraphs 26 through 45; and (iii) requiring the NPA to publish corrective advertising;

B. Morton Grove's court costs and reasonable attorney's fees; and

C. For such other and further relief as this Court deems equitable and just.

Dated: August 18, 2008

Respectfully Submitted,

MORTON GROVE
PHARMACEUTICALS, INC.

By: /s/ W. Gordon Dobie
One of its Attorneys

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of August 2008, I caused a copy of the **Amended Complaint** to be served on counsel of record via ECF electronic filing:

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